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*Admitted only in Maryland * Admitted only in Virginia •Practice Limited to Federal Agencies

July 27, 2004

WRITER'S DIRECT NUMBER: (202) 772-8615 INTERNET ADDRESS: FRANKÒ@SKGF.COM

Art Unit 1615

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 09/972,913; Filed: October 10, 2001

Use of Clioquinol for the Therapy of Alzheimer's Disease

Inventors:

BUSH et al.

Our Ref:

0609.4540003/TJS/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Fee Transmittal Form (PTO/SB/17);
- 2. Information Disclosure Statement;
- 3. Listing of the cited documents on Form PTO-1449 (55 sheets);
- A copy of five (5) of the cited documents on Form PTO-1449; 4.
- 5. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover the IDS fee; and
- 6. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLL.c.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skqf.com

Commissioner for Patents July 27, 2004 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottylun

Frank R. Cottingham Attorney for Applicants Registration No. 50,437

FRC/pcd Encls.

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(Complete (if applicable))

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uly 27, 2004

Telephone

Date

50,437

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
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Effective 10/01/2003. Patent fees are subject to annual revision.

X Applicant claims small entity status. See 37 CFR 1.27

SUBMITTED BY

Frank R. Cottingham

Name (Print/Type)

Signature

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espond to a collection of information unless it displays a valid CNMB control number.						
Complete if Known OIPE						
Application Number	09/972,913	10				
Filing Date	October 10, 2001	o 7 assa				
First Named Inventor	Ashley I. BUSH	-30L 2 / 2004 H				
Examiner Name	Sheikh, H.	2.				
Art Unit	1615	RADEMAR				
Attorney Docket No.	0609.4540003/TJS/FR	C				

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
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Deposit Account: the fees to Deposit Acct. No. 19-0036. Deposit Account 19-0036			Fee Code	Fee (\$)	Fee Description	Fee Paid
Number	1051 1	130	2051	65	Surcharge - late filing fee or oath	
Deposit Account Name Sterne, Kessler, Goldstein & Fox P.L.L.C.	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
The Director is authorized to: (check all that apply)	1053 1	130	1053	130	Non-English specification	
X Charge fee(s) indicated below X Credit any overpayments	1812 2,	,520	1812	2,520	For filing a request for ex parte reexamination	
Charge any additional fee(s) or any underpayment of fee(s)	1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805 1,	,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
	1251	110	2251	55	Extension for reply within first month	
FEE CALCULATION	1252	420	2252	210	Extension for reply within second month	
1. BASIC FILING FEE Large Entity Small Entity	1253	950	2253	475	Extension for reply within third month	
Fee Fee Fee Fee Fee Description Fee Paid Code (\$)	1254 1,	480	2254	740	Extension for reply within fourth month	
1001 770 2001 385 Utility filing fee	1255 2,	010	2255	1,005	Extension for reply within fifth month	
1002 340 2002 170 Design filing fee	1401	330	2401	165	Notice of Appeal	
1003 530 2003 265 Plant filing fee	1402	330	2402	165	Filing a brief in support of an appeal	
1004 770 2004 385 Reissue filing fee	1403	290	2403	145	Request for oral hearing	
1005 160 2005 80 Provisional filing fee	1451 1,	510	1451	1,510	Petition to institute a public use proceeding	
SUBTOTAL (1) (\$)	1452	110	2452	55	Petition to revive - unavoidable	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1453 1,	330	2453	665	Petition to revive - unintentional	
Fee from	1501 1,	330	2501	665	Utility issue fee (or reissue)	
Extra Claims below Fee Paid	1502	480	2502	240	Design issue fee	
Total Claims 20 **=	1503	640	2503	320	Plant issue fee	
Claims	1460	130	1460	130	Petitions to the Commissioner	
	1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
Large Entity Small Entity Fee Fee Fee Fee Fee Description	1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
Code (\$) Code (\$)	8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1202 18 2202 9 Claims in excess of 20 1201 86 2201 43 Independent claims in excess of 3	1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1203 290 2203 145 Multiple dependent claim, if not paid	1810	770	2810	385	For each additional invention to be	
1204 86 2204 43 ** Reissue independent claims over original patent	4004		2004	205	examined (37 CFR 1.129(b))	
, , , , , , , , , , , , , , , , , , ,		770	2801	385	Request for Continued Examination (RCE)	
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent	1802	900	1802	900	Request for expedited examination of a design application	
SUBTOTAL (2) (\$)	Other fee	e (spe	ecify) _			
**or number previously paid, if greater; For Reissues, see above	*Reduce	ed by	Basic f	Filing Fo	ee Paid SUBTOTAL (3)	180.00

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Registration No.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bush et al.

Appl. No. 09/972,913

Filed: October 10, 2001

For: Use of Clioquinol for the

Therapy of Alzheimer's Disease

Confirmation No. 5681

Art Unit:

1615

Examiner:

Sheikh, H.

Atty. Docket: 0609.4540003/TJS/FRC

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents AF1, AG1, AH1, AI1 and AJ1 are submitted herewith. Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/224,953, Bush et al., filed January 4, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham Attorney for Applicants Registration No. 50,437

trank R. Catty

Date: July 27, 2004 1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600 Page 1 of 55

APPLICATION NO.
0609.4540003/TJS/FRC
09/972,913

FIRST NAMED INVENTOR

Bush et al. INFORMATION DISCLOSURE STATEMENT FILING DATE ART UNIT October 10, 2001 1615 U.S. PATENT DOCUMENTS **EXAMINER** DATE CLASS SUB-CLASS FILING DATE INITIAL DOCUMENT NUMBER NAME 04/26/1993 5,373,021 12/13/1994 Marangos AA1 Raad et al. 10/03/1994 AB1 5,688,516 11/18/1997 AC1 5,688,651 11/18/1997 Solomon 12/16/1994 5,705,401 01/06/1998 | Masters et al. 09/16/1994 AD1 5,721,106 02/24/1998 Maggio et al. 09/12/1994 AE1 AFI 5,980,914 11/09/1999 Gerolymatos 02/13/1998 5,994,323 11/30/1999 Gerolymatos 02/13/1998 AG1 6,001,852 12/14/1999 Gerolymatos 02/13/1998 AH1 AI1 6,323,218 11/27/2001 Bush et al. 03/11/1998 Bush et al. 09/21/2001 AJ1 2002/0082273 06/27/2002 ΑK FOREIGN PATENT DOCUMENTS **EXAMINER** SUB-CLASS TRANSLATION INITIAL DOCUMENT NUMBER DATE COUNTRY CLASS WO 92/18111 10/29/1992 **WIPO** ALI No Yes AM1 WO 93/10459 05/27/1993 **WIPO** No Yes WO 93/24451 12/09/1993 WIPO ANI No Yes WO 94/04167 03/03/1994 WIPO AO1 No Yes AP1 WO 95/31199 11/23/1995 **WIPO** No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Assaf, S.Y., and Chung, S-H., "Release of endogenous Zn²⁺ from brain tissue during AR 1 activity," Nature 308:734-736, Nature Publishing Group (April 1984) Atwood, C.S., et al., "Dramatic Aggregation of Alzheimer A β by Cu(II) Is Induced by Conditions Representing Physiological Acidosis," J. Biol. Chem. 273:12817-12826, AS 1 American Society for Biochemistry and Molecular Biology (May 1998) Bacon, P.A., et al., "Rheumatoid Disease, Amyloidosis and its Treatment with ΑT 1 Penicillamine," Eur. J. Rheum. Inflamm. 2:70-74, Cameron Publishers (1979)

FORM PTO-1449

EXAMINER DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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APPLICATION NO.				

O609.4540003/TJS/FRC

09/972,913

FIRST NAMED INVENTOR

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT

considered. Include copy of this form with next communication to Applicant.

Bush et al. FILING DATE ART UNIT October 10, 2001 1615

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	AM2	W	O 96/12544	05/02/1996	WIPO			Ye
	AN2	W	96/28471	09/19/1996	WIPO			Ye No
	AO2	W	O 97/04794	02/13/1997	WIPO			Ye No
	AP2	W	O 97/09976	03/20/1997	WIPO			Ye No
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	AS	2			Conformations and Aggreimer's Disease," <i>J. Mol. E</i>			
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	FIRST NAMED INVENTOR Bush et al.	
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	AR	Behl, C., <i>et al.</i> , 77:817-827, Ce		eroxide Mediates Amylo 1994)	oid β Protein 1	Γoxicity," Co	ell		
	AS	Biaglow, J.E., and Kachur, A.V., "The Generation of Hydroxyl Radicals in the Reaction of Molecular Oxygen with Polyphosphate Complexes of Ferrous Ion," <i>Radiat. Res.</i> 148:181-187, Kluge Carden Jennnings Pub. Co. (August 1997)							
	AT	Alzheimer's Dis	Boado, R.J., et al., "Drug Delivery of Antisense Molecules to the Brain for Treatment of Alzheimer's Disease and Cerebral AIDS," J. Pharm. Sci. 87:1308-1315, American Pharmaceutical Association (November 1998)						
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ATTY. DOCKET NO. 0609.4540003/TJS/FRC FIRST NAMED INVENTOR APPLICATION NO. 09/972,913

Page 4 of 55

Bush et al. FILING DATE

October 10, 2001

ART UNIT 1615

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	AS	<u>5</u>	Busciglio, J., and Yankner, B.A., "Apoptosis and increased generation of reactive oxygen species in Down's Syndrome neurons <i>in vitro</i> ," <i>Nature 378</i> :776-779, Nature Publishing Co. (December 1995)					
	AT	Bush, A.I., et al., "A Novel Zinc(II) Binding Site Modulates the Function of the βA4 Amyloid Protein Precursor of Alzheimer's Disease," J. Biol. Chem. 268:16109-16112, American Society for Biochemistry and Molecular Biology (August 1993)						
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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	FORM PTO-1449 DISCLOSURE STATEMENT

Page 6 of 55

ATTY. DOCKET NO. APPLICATION NO. 0609.4540003/TJS/FRC 09/972,913

FIRST NAMED INVENTOR
Bush et al.

FILING DATE ART UNIT
October 10, 2001 1615

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FIRST NAMED INVENTOR	
Bush et al.	
FILING DATE	ART UNIT
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INFORMATION DISCLOSURE STATEMENT	Bush et al.	
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	АТ	9	Coyle, J.T., and Puttfarcken, P., "Oxidative Stress, Glutamate, and Neurodegenerative Disorders," <i>Science 262</i> :689-695, American Association for the Advancement of Science (October 1993)					
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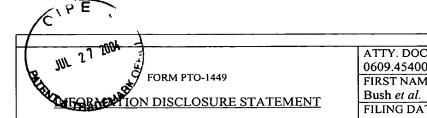
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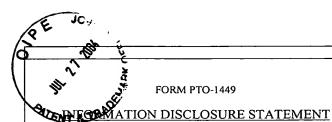
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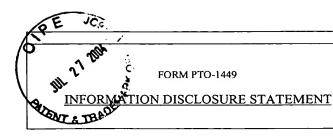
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	AS	<u>38</u>	Roberts, G.W., 338:1422-1423,	<i>et al.</i> , "βΑ4 Lancet Pul	l amyloid protein deposit blishing Group (Decemb	tion in brain afte er 1991)	er head traun	na," <i>Lancet</i>
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